

**SBM contribution to TRIS notification 2021/42/D (Germany) -**

**Ordinance on the reorganisation of secondary national legislation on biocidal products**

In its opening statement, the draft notification states that the EU regulation only contains general principles for the use of biocidal products but does not give concise instructions, and postulates a high potential risk to human health, non-target organisms and the environment of (authorised) products. This problem is to be addressed by providing the user with information at the point of sale.

While we fully agree that the user of any biocidal product needs to be informed about the potential harm a product can cause, we consider any adult user capable of reading and following the instructions for use as given on the label of each product, as expected of them for cleaning products, medicine, paints, etc. We would like to stress that products intended for the general public are already of low risk (excluding certain hazard categories according to BPR Art. 19). The measures proposed in the draft act and the resulting impact on the trade are disproportionate, while the assumed benefits are not based on reliable data. We therefore support and refer to the comments submitted by the German industry association (Industrieverband Agrar e.V.).

In addition, we would like to express our disagreement with §15, which aims at excluding certain active substances from products approved for the user categories ‚general public‘ and ‚professional users‘. This provision completely dismisses the risk assessment performed for a product that may well be available in many other member states for the general public, and introduces a national hazard based approach without any argumentation. It also places the burden of proof for the necessity of the product according to points (b) and (c) of the first sentence of Article 5(2) of Regulation (EU) No 528/2012 on the applicant – after this assessment has already been performed for the active substance at EU level.

In fact, this article could have severe practical implications, as illustrated by the following example: only one product is currently approved for use against rats by the German general public. Since rats are notoriously suspicious and infestations therefore virtually impossible to eradicate with mechanical means alone, a chemical solution must be available. This is underlined by the fact that rats are mandatory to combat and must be notified to the authorities, being carriers of human disease.

The active substance in the product is coumatetralyl, a first-generation anticoagulant and affected by the stipulations in §15. This only product approved in Germany, at < 30 ppm, is not classified according to CLP, neither for health nor for environment. All other active substances available to trained professional users for use against rats can not be authorised for use by the general public, but are already banned at national level (second-generation anticoagulants) or at EU level (cholecalciferol). Nevertheless, the „Final report on Risk Mitigation Measures For Anticoagulant Rodenticides As Biocidal Products“ (European Commission, 2014) comes to the conclusion that solutions should be available for all user categories and can be properly managed by appropriate risk mitigation measures (which have since been implemented across Europe with the renewal decisions for all anticoagulants). Measures include the mandatory use of tamper-resistant bait boxes and limitations on the available pack size.

This example shows that sufficient measures are available at EU level, and that further restrictions at national level are not necessary or even contra-indicative. If these restrictions were to be implemented, this could lead to refusal of necessary pest control solutions and unavailability of legal, effective means to the German consumer. In consequence, illegal products (e.g. chemical solutions or glue traps) will see an increased demand, as consumers might shy away from the high costs associated with hiring a professional pest-control service provider. It is also extremely doubtful that PCOs alone could cover all rat infestations in German households, so number and severity of rat infestations in private homes are likely to increase. This would be completely contrary to the sense of this draft act.

**In conclusion SBM view this German ordinance, and specifically §15, as inappropriate and disruptive to the German market.**